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UNITED STATES of AMERICA, ex rel. JEFFREY A. SMITH

EDL

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

C 05 4055

UNITED STATES of AMERICA, ex rel. JEFFREY A. SMITH, Plaintiff, vs. SCIOS, INC., a Delaware Corporation, and JOHNSON & JOHNSON, a New Jersey Corporation, Defendants.	Case No. **COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT (31 U.S.C. 3729, et seq.); DEMAND FOR JURY TRIAL**

PLAINTIFF/RELATOR, JEFFREY A. SMITH, an individual, on behalf of THE GOVERNMENT OF THE UNITED STATES OF AMERICA ("PLAINTIFF") alleges as follows:

RELATOR

1. RELATOR, JEFFREY A. SMITH ("SMITH") (*Qui Tam* Plaintiff) is and at all times mentioned herein was, an individual citizen of the State of California. At all times relevant hereto, SMITH was an employee of Defendant, SCIOS, INC. ("SCIOS"), working in the capacity of Regional Business Director. In the course and scope of his employment with SCIOS, SMITH sold the pharmaceutical NATRECOR, generic name Neseretide, to physicians. As Regional Business Director, SMITH was intimately familiar with SCIOS's marketing strategy with

respect to NATRECOR and privy to highly confidential meetings and discussions relating to the same. SMITH is an "original source" as defined in 31 U.S.C. 3730(e)(4)(B), and has personal knowledge of all facts alleged herein.

DEFENDANTS

2. PLAINTIFF is informed and believes, and on such grounds alleges, DEFENDANT, SCIOS is a corporation incorporated under the laws of the state of Delaware, having its principal place of business in the State of California. At all times relevant hereto SCIOS was engaged in the business of promoting, marketing and distributing the pharmaceutical NATRECOR. SCIOS does business in the State of California and throughout the United States, and at all times relevant it developed, manufactured, and sold in interstate commerce and in California NATRECOR.

3. PLAINTIFF is informed and believes, and on such grounds alleges, JOHNSON & JOHNSON ("J&J") is a corporation incorporated under the laws of the state of New Jersey, having its principal place of business in the State of New Jersey.

4. This case is filed under seal pursuant to the provisions of 31 U.S.C. § 3730(b)(2).

5. PLAINTIFF is informed and believes, and on such grounds alleges that Defendant SCIOS is a wholly owned subsidiary of Defendant J&J and the J&J actively and intentionally directed and controlled the actions of SCIOS as described herein and reaped the benefits of SCIOS's sale of the NATRECOR product.

JURISDICTION AND VENUE

6. This is an action to recover damages and civil penalties in excess of one hundred million dollars ($100,000,000.00) on behalf of the United States of America arising out of false claims presented by Defendants, SCIOS and J&J under the Federal Medicare Program. This action arises under the provisions of Title 31 U.S.C. Section 3729, et seq., hereinafter referred to generally as "the False Claims Act."

7. This court has jurisdiction pursuant to 31 U.S.C. § 3732(a).

8. Venue lies in this district pursuant to 31 U.S.C. § 3732(a), which provides that any action may be brought in any judicial district where the defendant can be found, where the defendant resides, where the defendant transacts business, or in which any act proscribed by Section 3729 occurred, as the Defendant transacts business, may be found, and engaged in proscribed conduct in this Division and District.

FACTUAL ALLEGATIONS

9. SCIOS launched the NATRECOR product in or around June of 2001.

10. NATRECOR is approved by the FDA for the intravenous treatment of patients with acutely decompensated congestive heart failure who have dyspnea at rest or with minimal activity.

11. In laymen's term NATRECOR is approved for use in the acute care setting, i.e.: in the hospital, when a patient presents with the inability to breathe, due to congestion.

12. Immediately after its approval by the FDA, SCIOS began expanding NATRECOR's use into two (2) off-label areas.

13. One off-label use of NATRECOR is Out Patient Infusion ("OPI"). In this scenario, a patient comes to a physician's office for a routinely scheduled infusion, known as a serial or intermittent infusion. There presently exists no consistent or meaningful data on the use of NATRECOR in this setting.

14. SCIOS took the following steps to actively promote NATRECOR for off-label OPI use:

a. Employed an active brand manager to develop business and marketing tactics and sales forecasts around this market. The calendar year 2005 forecast for OPI was approximately 30% of NATRECOR sales by SCIOS , or approximately $150,000,000.00. This figure represents only the drug acquisition cost.

b. Hired a reimbursement team to actively show physicians how physicians can make money by administering NATRECOR in their offices. This team developed a reimbursement handbook describing the various billing codes for in-office infusions. This team also proactively worked with Medicare intermediaries to secure reimbursement. In addition, sales representatives would put together spread sheets on the profitability of OPI to distribute to physicians.

c. Lobbied various Medicare intermediaries to pay for NATRECOR in the OPI setting. SCIOS directed their sales representatives to garnish physician and patient letters of support to encourage reimbursement, even though there was no definitive data or approved labeling for serial infusions.

d. Awarded sales representatives by paying on a per vial basis and encouraged their representatives to sell NATRECOR in the OPI setting by allowing physicians to fax their invoices in for the sales representatives to be paid. Compensation to sales representatives ranged from $60-100 per vial, on a vial selling for less than $400. Sales representatives were making upwards of $100,000.00 to $200,000.00 per year in bonus by selling NATRECOR in the OPI setting. This is in addition to their over $200,000.00 standard compensation package including salary, car, and options. In other words, sales representatives were rewarded for the off-label marketing of NATRECOR .

e. All SCIOS Business plans would discuss the OPI market and require sales representatives to pursue the OPI market.

f. Sponsored CME and Promotional-type programs for physicians selling the concept of serial infusion. Over 1,000 programs of this type were offered per year between 2001 and the present.

g. Employed guest speakers at all sales meetings to educate and encourage sales representatives to pursue the OPI market with respect to NATRECOR sales.

15. In addition to the OPI uses described above, SCIOS also marketed the NATRECOR product for off-label use in Pre-, Peri- and Post-Surgical settings.

16. SCIOS took the following steps to actively promote NATRECOR for off-label use in Pre-, Peri- and Post-Surgical settings:

a. Provided training at all sales meetings to their sales representatives, with surgeons who were currently using NATRECOR for off-label use.

b. Developed a strategy to have the Scientific Account Managers conduct so-called "advisory meetings" to educate customers on off-label areas. SCIOS would then have those sales representatives put together meetings to educate other customers regarding what they had learned at the "advisory meetings."

c. Developed a story regarding the renal protective properties of NATRECOR during CT surgery and had their sales representatives relay this message to their customers.

d. Developed business plans on revenue and tactics to engage in this market.

e. Conducted SCIOS sponsored CME activity to lure physicians to using NATRECOR off-label.

17. SMITH is informed and believes and thereon alleges that the herein-described conduct of SCIOS relating to the off-label marketing of NATRECOR persists to the present day.

COUNT I - OFF-LABEL PROMOTION

18. SMITH realleges the allegations set forth in Paragraphs 1 through 17 as though fully set forth herein.

19. SCIOS, by its previously detailed actions, defrauded the United States of America, Food and Drug Administration (FDA), by engaging in a scheme to

promote the use of NATRECOR in a manner inconsistent with the FDA labeling requirement (i.e., for the intravenous treatment of patients with acutely decompensated congestive heart failure who have dyspnea at rest or with minimal activity).

20. Unknown to the FDA, SCIOS actively engaged in the marketing of NATRECOR for OPI and Pre-, Peri- and Post-Surgical Settings in a calculated effort to circumvent federal law.

21. As a result of off-label sales of NATRECOR for use in a manner inconsistent with the FDA labeling requirement, the Federal Government has and continues to remit millions upon millions of dollars in reimbursement for the off-label sales of NATRECOR.

COUNT II - VIOLATIONS OF 31 U.S.C. § 3729

22. SMITH realleges the allegations set forth in Paragraphs 1 through 21 as though fully set forth herein.

23. But for SCIOS scheme to promote NATRECOR in an off-label fashion, the government would not be exposed to this current and future Medicare/Medicaid reimbursement liability. The actions of SCIOS constituted a fraud on the government in that:

a. SCIOS knowingly presented or caused to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval (in violation of 31 U.S.C. § 3729(a)(1)).

b. SCIOS knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the government (in violation of 31 U.S.C. § 3729(a)(2)).

c. SCIOS conspired to defraud the government by getting a false or fraudulent claim allowed or paid (in violation of 31 U.S.C. § 3729(a)(3)).

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DISCLOSURE OF MATERIAL EVIDENCE AND INFORMATION IN POSSESSION OF RELATOR

24. SMITH realleges the allegations set forth in Paragraphs 1 through 23 as though fully set forth herein.

25. Relator SMITH has in his possession the following information germane to the case:

a. Confidential marketing material distributed by SCIOS detailing the off-label marketing strategy

b. Computer files, including inter-office memoranda and sales forecasts relating to the off-label marketing of NATRECOR copied from his notebook computer used during his employ with SCIOS;

c. Personal knowledge of information distributed by SCIOS during sales strategy meetings during the course of his employ with SCIOS.

26. Relator has also provided notice of all of the above to the Department of Justice and to Assistant Unites States Attorney Sara Winslow, with the U.S. Attorney's Office, Civil Division, located at 450 Golden Gate Ave., 10th Floor, San Francisco, CA 94102-3495, telephone: (415) 436-6925.

DEMAND FOR JURY TRIAL

Plaintiff/Relator SMITH hereby demands trial by jury.

Respectfully submitted under seal this 7th day of October, 2005.

Dated: October 7, 2005

BREMER WHYTE BROWN & O'MEARA LLP

By: _____
Monique R. Linson
Attorneys for Plaintiff
UNITED STATES of AMERICA, ex rel. JEFFREY A. SMITH